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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/652,498  | 09/02/2003  | Randolf Von Oepen    | 17601.16a.1.1.1     | 2721             |
| 57360 7590 12/15/2008<br>WORKMAN NYDEGGER<br>1000 EAGLE GATE TOWER,<br>60 EAST SOUTH TEMPLE<br>SALT LAKE CITY, UT 84111 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| PELLEGRINO, BRIAN E   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3738  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### Office Action Summary

**Application No.**

10/652,498

**Applicant(s)**

VON OEPEN, RANDOLF

**Examiner**

Brian E. Pellegrino

**Art Unit**

3738

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 8, 10, 16, 21, 23, 24 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 10, 16, 21, 23, 24 and 30-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_



## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/19/08 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,8,10,21,23,24,30-33,35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Pinchuk et al. (EP 861638). Glastra et al. show (Fig. 6) a stent-catheter arrangement having a balloon **26** with two fully expandable "substantially cylindrical" sections **27** and a "substantially cylindrical" section of reduced expandability between the expandable sections. The examiner is interpreting the claimed elements "substantially cylindrical" in this way: something that is in the form of a conduit having a hollow or cylindrical like cross-section. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed.



Cir. 1997 127 F3d 1048, 1054,1055. However, Glastra does not disclose a liquid impermeable cover over the stent or a stiffening element for forming a reduced expandable section. It is noted that Glastra shows (Fig. 6) a flared stent with reduced cross section. Also note the middle sections are coupled by tapered sections.

Pinchuk also illustrates (Figs. 8-11) a stent **100** that is flared and can be considered as a substantially cylindrical deformable stent to extend over a balloon catheter. Pinchuk also teaches the stent has a graft (which is well known in the art to be liquid impermeable), col. 7, line 49. Pinchuk additionally teaches (Fig. 11) an independent stiffening element **105'** can be used to form a section of reduced expandability **106'**. It would have been obvious to one of ordinary skill in the art to use a blood impermeable cover on the stent and a stiffening element as taught by Pinchuk with the stent-catheter system of Glastra et al. in order to provide an outer surface that does not allow blood leakage and to provide a throttle portion to increase blood flow to reduce the likelihood of plaque buildup. Please note claims 16,23,24 are being interpreted as product-by-process claims and are not construed as being limited to the product formed by the specific processes recited. The balloon of Glastra is thus "selectively" stiffened since it is not given any special meaning.

Regarding claims 2,3,8,21,35 Pinchuk et al. disclose graft material is a "foil" of body-tolerated material, such as the polymer PTFE, col. 1, lines 48-50.

With respect to claims 10,23,24,32,33 Pinchuk also discloses that stiffening the midsection or segments of the apparatus is accomplished by placing rings about the surface of the stent and can be accomplished in a secondary process such as bonding,



col. 7, lines 10-16,21-24. Please note the Examiner is not giving any special meaning to "selectively stiffened" as this can be accomplished in a variety of ways.

Regarding claims 36,37, the flared ends of the stent or "fixing portions" are configured to achieve blood throttling in the vessel and the tapered portions are configured to minimize blood turbulence in the vessel.

Claims 16,34,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Pinchuk et al. (EP 861638) as applied to claim 1 above, and further in view of Crocker et al. (5843116). Glastra in view of Pinchuk is explained supra. However, Glastra as modified by Pinchuk fail to disclose the stiffening elements are within the balloon segments in the reduced diameter section. Crocker et al. show (Fig. 3) that stiffening material is integrated into balloons to limit the expansion of the balloon in certain areas, col. 5, lines 29-49. Crocker also teaches bonding, col. 6, lines 8-10. It would have been obvious to one of ordinary skill in the art to use the teaching of Crocker et al. that stiffening material can be incorporated into balloons and place the stiffening elements of Pinchuk et al. within the balloon of Glastra such that the elements are non-obtrusive and do not become unattached since Pinchuk taught separate elements. It would be an obvious expedient to eliminate the risk of stiffening elements from detaching during use of the apparatus by integrating them in the balloon.

### ***Response to Arguments***

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grayzel (4796629) discloses stiffening a balloon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738